UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Washington, D.C. 20460

OFFICE OF

GENERAL COUNSEL

AUG 23 2018

Honorable Jeffrey H. Wood
Acting Assistant Attorney General
Environment and Natural Resource Division
U.S. Department of Justice
P.O. Box 7754
Ben Franklin Station
Washington, D.C. 20530

Re: *LULAC v. Wheeler*, No. 17-71636 (9th Cir. Aug. 9, 2018)

Dear ~~Mr. Wood:~~ Jeff

The Environmental Protection Agency ("EPA") requests that the Department of Justice ("Department") seek rehearing in the above-captioned Federal Food, Drug and Cosmetic Act ("FFDCA") and Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") case. The split Ninth Circuit opinion in *LULAC v. Wheeler* vacated EPA's March 29, 2017 denial of a 2007 administrative petition that sought to effectively ban the use of chlorpyrifos – by weight, the most widely used insecticide in the United States – under both the FFDCA and FIFRA. The majority held that the court had jurisdiction to review the denial order under the FFDCA, that petitioners were not required to exhaust administrative remedies before bringing suit, and that EPA's denial was unlawful because EPA failed to apply the FFDCA safety standard to its review of the petition. The court vacated the denial order and directed EPA to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations within 60 days. The dissent agreed with EPA's reading of the FFDCA, arguing that the court lacked jurisdiction to review FFDCA denial orders, noting that 21 U.S.C. § 346a(h) only provides for judicial review of EPA's response to the administrative objections to a denial, but provides for no direct review of denial orders themselves and precludes review of these matters under any other law.

EPA requests that the Department seek both panel and *en banc* rehearing of the majority's holding that it had jurisdiction to review the denial order and the court's remedy directing EPA to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations in 60 days. As explained below, EPA believes there are distinct aspects of both the court's jurisdictional and remedy rulings that are appropriate for the *LULAC* panel and for an *en banc* panel to separately review.

STATUTORY BACKGROUND

EPA regulates pesticides under both the FFDCA, *see* 21 U.S.C. § 346a, and FIFRA, 7 U.S.C. §§ 136-136y. The FFDCA authorizes EPA to establish "tolerances," which are maximum levels of pesticide residue allowed in or on food. 21 U.S.C. § 346a(a). EPA may only establish a tolerance for a pesticide if it determines that the tolerance is "safe." *Id.* § 346a(b)(2)(A)(i). Without a tolerance or exemption, pesticide residues in or on food are considered unsafe. *Id.* § 346a(a). Section 346a(b)(2)(A)(ii) defines "safe" as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This standard does not allow for the consideration of the economic benefits from the use of a pesticide. EPA must revoke or modify a tolerance if it determines that the tolerance is not safe. *Id.* § 346a(b)(2)(A)(i). An unsafe food is considered "adulterated" and may not be moved in interstate commerce legally. *Id.* §§ 331(a), 342(a)(2)(B), 346a(a).

The FFDCA sets forth a multi-stage procedural framework for the establishment, modification, or revocation of tolerances. The first stage may be initiated by EPA acting on its own accord or in response to an administrative petition. *Id.* § 346a(d)(1), (e)(1). "Any person may file with [EPA] a petition proposing the issuance of a regulation . . . establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." *Id.* § 346a(d)(1)(A). EPA must then give "due consideration" to the petition and take one of three actions: (i) issue a final regulation establishing, modifying, or revoking a tolerance; (ii) issue a proposed regulation under the separate provisions of § 346a(e), and thereafter issue a final regulation after additional public notice and comment; or (iii) issue an order denying the petition. *Id.* § 346a(d)(4)(A).

When EPA issues a regulation establishing, modifying, or revoking a tolerance, or an order denying a petition to take such action, that regulation or order takes effect upon publication unless the regulation or order specifies otherwise. *Id.* § 346a(g)(1). The FFDCA provides that within 60 days following the issuance of that regulation or order any person may file written objections with EPA. EPA may stay the effectiveness of the order or regulation if objections are filed. *Id.* Objectors may also request an evidentiary hearing on their objections. *Id.* § 346a(g)(2)(B). After considering any objections and any hearing, if held, EPA must issue a final order with respect to the objections as soon as practicable. *Id.* § 346a(g)(2)(C). Such an order is subject to judicial review in the United States Courts of Appeals. *Id.* § 346a(h)(1). Importantly, § 346a(h) does not provide for direct review of a final rule or petition denial order under § 346a(d)(4)(A). Furthermore, the FFDCA precludes judicial review of any issue that is reviewable under subsection (h) under any other provision of law. *Id.* § 346a(h)(5).

EPA also regulates pesticides under FIFRA. While the FFDCA authorizes the establishment of legal limits for pesticide residues in or on food, FIFRA requires EPA approval

of pesticide products themselves prior to their distribution or sale and establishes a registration regime for regulating the use of pesticides. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5). FIFRA explicitly requires EPA to address the FFDCA's safety standard for pesticides when assessing whether a pesticide can be registered, to the extent that the registered use will leave residues in or on food. FIFRA does this by defining the term "unreasonable adverse effects on the environment" in part to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21 [i.e., the 'reasonable certainty of no harm' standard]." 7 U.S.C. § 136(bb). If, however, a pesticide product is not registered for any use that would result in residues in or on food, its registration is not evaluated under this part of § 136(bb), but rather, under only the provision that defines "unreasonable adverse on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This standard, unlike the FFDCA safety standard, requires EPA to take into account both the risks and benefits of a pesticide's use in determining whether a pesticide should be registered or cancelled.

It is important to note that the revocation of tolerances under FFDCA does not automatically cancel the registrations under FIFRA of pesticides that are registered for use on food. Although EPA must coordinate its actions under these statutes, the requirements for revocation and cancellation are statutorily and regulatorily distinct. *See* 21 U.S.C. §346a(l) (directing EPA to coordinate necessary revocation and cancellation actions under each statute). In order to cancel a pesticide's registration, EPA must comply with the procedures set forth in 7 U.S.C. § 136d(b) of FIFRA unless the cancellation is voluntary. Before EPA may issue a final cancellation order under that subsection, at least 60 days prior to issuing any notice of intent to cancel a pesticide, EPA must first provide the United States Department of Agriculture and the FIFRA Scientific Advisory Panel with an opportunity to review the notice. § 136d(b). EPA must then provide the registrants of the pesticide with 30 days' notice of its intent to cancel the pesticide. *Id.* During that period, a person adversely affected by the notice may request a formal adjudicatory hearing as provided in § 136d(b),(d). The conduct of any hearing is directed by an administrative law judge and neither the statute nor the regulations place a limit on the length of the proceedings. *See* § 136d(d); 40 C.F.R. Part 164 subpart B.

REGULATORY BACKGROUND

In September 2007, Pesticide Action Network North America ("PANNA") and Natural Resources Defense Council ("NRDC") submitted to EPA a joint petition to revoke all FFDCA tolerances and cancel all FIFRA registrations for chlorpyrifos (the "Administrative Petition"). The Administrative Petition raised ten claims. EPA provided PANNA and NRDC with two interim responses on July 16, 2012, and July 15, 2014, which denied six of their ten claims in full, and granted in part and denied in part a seventh claim. The remaining claims all related to same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in

children at exposure levels below EPA's existing regulatory standard (10% acetylcholinesterase inhibition).[1]

In September 2014, PANNA and NRDC filed a petition for writ of mandamus. In 2015, the Ninth Circuit issued a writ of mandamus and ordered EPA to "issue either a proposed or final revocation rule or a full and final response" to the Administrative Petition by October 31, 2015. *In re PANNA*, 798 F.3d 809 (9th Cir. 2015). The Court then ordered EPA to take final action on the Administrative Petition by March 31, 2017. *In re PANNA*, 808 F.3d 402, 402-03 (9th Cir. 2015); *In re PANNA*, 840 F.3d 1014, 1015 (9th Cir. 2016).

In November 2015, EPA proposed to respond to the Administrative Petition by revoking all chlorpyrifos tolerances based in part on uncertainty surrounding the potential for chlorpyrifos to cause neurodevelopmental effects. 80 Fed. Reg. 69,079. In November 2016, EPA published a notice of data availability that released for public comment EPA's revised risk assessment that proposed a new regulatory point of departure based on the potential for chlorpyrifos to result in adverse neurodevelopmental effects. EPA continued to propose in that notice that the tolerances failed to meet the FFDCA standard. 81 Fed. Reg. 81,049 at 81,050.

On March 29, 2017, EPA denied the Administrative Petition. 82 Fed. Reg. 16,581. EPA determined that the public comments submitted in connection with EPA's proposed revocation "suggest that there continue to be considerable areas of uncertainty with regard to what the epidemiology data show and deep disagreement over how those data should be considered in EPA's risk assessment." *Id.* at 16,590. EPA concluded that,

> [D]espite several years of study, the science addressing neurodevelopmental effects remains unresolved and that further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos. EPA has therefore concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution on those issues. As noted, Congress has provided that EPA must complete registration review by October 1, 2022. Because the 9th Circuit's August 12, 2016 order has made clear, however, that further extensions to the March 31, 2017 deadline for responding to the Petition would not be granted, EPA is today also denying all remaining petition claims.

Id. at 16,583.

[1] Acetylcholinesterase ("AChE") is an enzyme necessary for the proper functioning of the nervous system and inhibition of AChE is the mechanism through which chlorpyrifos acts against insect pests. At high enough doses, chlorpyrifos can reduce AChE activity sufficiently to cause adverse effects in humans and wildlife.

On July 18, 2017, in response to Petitioners' request for additional mandamus relief, the Ninth Circuit concluded that EPA's March 29, 2017 denial order complied with the court's order on mandamus, and in strongly worded dicta the court indicated that it could not review a challenge to the denial order, but only a future EPA order on objections to the denial order: "Now that EPA has issued its denial, substantive objections must first be made through the administrative process mandated by statute. PANNA implicitly recognizes as much by acknowledging that '[f]iling objections and awaiting their resolution by the EPA Administrator is a prerequisite to obtaining judicial review' of EPA's final response to the petition. Only at that point may we consider the merits of EPA's 'final agency action.'" *In re PANNA*, 863 F.3d 1131 1133 (9th Cir. 2017).

SUMMARY OF THE PANEL DECISION

On August 9, 2018, the Ninth Circuit vacated EPA's March 2017 order denying the Administrative Petition. Slip op. at 32. The court's order directed EPA to revoke all chlorpyrifos FFDCA food residue tolerances and cancel all chlorpyrifos FIFRA registrations within 60 days. *Id.* In so doing, the court rejected EPA's argument that the federal courts lack jurisdiction to hear challenges to an EPA order denying a petition under 21 U.S.C. § 346a(d)(4) and only have jurisdiction to review an EPA order responding to objections to the denial order under § 346a(g)(2)(C). Specifically, the court found that the judicial review provision in § 346a(h)(1) does not provide a clear indication of congressional intent that awaiting a response to administrative objections prior to bringing suit is a jurisdictional requirement and therefore that section does not preclude judicial review of petition denial orders. *Id.* at 15-25. Finding it had jurisdiction to hear the case under § 346a(h)(1), the court then held that petitioners were not required to first exhaust their administrative remedies (i.e., await EPA's response to objections) before bringing suit. *Id.* at 25-30. To support this finding, the court pointed to what it deemed the strong individual interests against requiring exhaustion and weak institutional interests in favor of it. *Id.* at 30. The court then turned to the merits of EPA's petition denial, found that there was no justification for the EPA's decision in its 2017 petition denial order in the face of EPA's 2016 risk assessment that found that "potential aggregate exposure [to chlorpyrifos] does not meet the FFDCA safety standard," and vacated the order. *Id.* at 31-32. The court also held that because FIFRA incorporates the FFDCA safety standard, chlorpyrifos registrations do not meet the FIFRA standard and must be cancelled. *Id.* The court ordered EPA to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations within 60 days.[2] *Id.*

Judge Fernandez issued a lengthy dissent, arguing that he would have dismissed the petition, as the court lacked jurisdiction over the petition for review under either FFDCA or FIFRA. *Id.* at 32-40. He also would have ruled that petitioners had not properly filed a petition for a writ of mandamus compelling completion of the administrative objections process and therefore could not raise their unreasonable delay arguments with the court. *Id.* at 40-42.

[2] On August 23, the Ninth Circuit granted the Government's motion to clarify that the 60-day period commences from the issuance of the court's mandate and not the date of the decision.

ISSUES FOR PANEL REHEARING

A petition for panel rehearing under Federal Rule of Appellate Procedure 40 is appropriate if, among other things, a material point of law was overlooked in the decision or an apparent conflict with another decision of the court was not addressed in the opinion. Consistent with this standard, EPA believes there are three primary issues for which panel rehearing is appropriate:

(1) The majority`s finding that it has jurisdiction to hear a challenge to an FFDCA petition denial is in conflict with the Ninth Circuit`s 1988 decision in *Nader v. EPA*, 859 F.2d 747 (9th Cir. 1988), which found that the courts of appeals lack jurisdiction to review EPA denials of FFDCA petitions to revoke tolerances and may only hear challenges to EPA orders responding to administrative objections following the petition denial.

(2) The court's direction to cancel all FIFRA registrations within 60 days suffers from two significant legal infirmities: *First*, contrary to the court`s finding, FIFRA does not incorporate the FFDCA safety standard for all chlorpyrifos products at issue in this matter, but only for those products registered for use on food (chlorpyrifos is registered for dozens of uses including use of food commodities as well as non-food uses such as turf and mosquito control). Products that are not registered for uses that will result in residues on food sold in commerce are instead subject only to the FIFRA "risk-benefit" standard under 7 U.S.C. § 136(bb) that requires EPA to balance the risks and benefits of use in determining whether the product should be registered or cancelled. The court therefore did not apply the appropriate standard in concluding that all chlorpyrifos products fail to meet the requirements of FIFRA. *Second*, the court`s direction to cancel all FIFRA registrations in 60 days would compel EPA to violate the procedural requirements of FIFRA, since, in the absence of a voluntary cancellation request from all registrants, § 136d(b) requires EPA to complete several lengthy procedural steps before issuing any final cancellation order, including providing the registrants with an opportunity for an adjudicatory hearing before an administrative law judge that is not subject to any statutory time limitation.

(3) While perhaps more an issue of clarification than of substantive reconsideration, the court's order to revoke all tolerances does not address whether that revocation is to be issued as a final order under § 346a(d)(4)(A)(iii), which would be subject to administrative objections and a request for an administrative stay or delayed effective date, or issued as a final reviewable order under § 346(g)(2)(C), which would bypass the objections process entirely and would be immediately subject to judicial review. EPA believes the latter approach would be inconsistent with the vacatur of the existing (d)(4) order and with the requirements of the FFDCA that compel EPA to consider administrative objections, but it is unclear what the court has directed in that respect.

Conflict with the Ninth's Circuit's 1988 Decision in Nader v. EPA

While the Federal Defendants cited for support on the jurisdictional issue the Second Circuit's decision in *NRDC v. Johnson*, 461 F.3d 164 (2d Cir. 2006) and the strong dicta from *In*

re PANNA, 863 F.3d 1131 1133 (9th Cir. 2017), the briefs did not include citation to any Ninth Circuit case that EPA could reasonably argue represented controlling Ninth Circuit precedent as to whether §346a(h)(1) provides a jurisdictional bar to direct challenges to FFDCA petition denial orders. *Nader v. EPA* is that case, and the court similarly did not address it in any fashion. The panel rehearing process should be used to correct that error. As with the present case, *Nader* addressed EPA's denial of a petition seeking revocation of tolerances for pesticide residues (in that case, the pesticide was daminozide, also known as Alar) under the FFDCA. At that time, EPA set tolerances only for raw agricultural commodities under § 346a; it set tolerances for processed food under § 348. When Congress amended the FFDCA as part of the Food Quality Protection Act of 1996, it collapsed EPA's tolerance-setting authority into a single section (§ 346a, as amended), and modified the administrative objections and judicial review provisions in § 346a(g) and (h) to mirror those provided in section § 348(f) and (g) (which require the submission of objections and an EPA order responding to such objections as a prerequisite to judicial review).[3] Thus, the *Nader* court's treatment of the objections and judicial review provisions in § 348(f) and (g) is directly relevant to the treatment of those matters under § 346a(g) and (h), and therefore relevant to the *LULAC* panel's review of EPA's chlorpyrifos petition denial order. In *Nader*, the Ninth Circuit held that it lacked jurisdiction under § 348(g) to hear a challenge to a petition denial order, finding that the only thing a court of appeals could hear was an EPA order following objections to a petition denial. As with current § 346a(h)(1), the judicial review language in § 348(g) that the *Nader* court reviewed only authorizes review of orders on objections following the issuance of a rule or a petition denial. Given the near identicality of the judicial review provisions in § 348(g) and current § 346a(h), the *Nader* case should have been viewed by the *LULAC* majority as controlling Ninth Circuit precedent.

It is nonetheless possible that the majority might wish to attempt to distinguish *Nader* in the same way it tried to distinguish *Gallo Cattle Co. v. United States Department of Agriculture*, 159 F.3d. 1194 (9th Cir. 1998) – as a case preceding more recent Supreme Court and Ninth Circuit case law admonishing against finding laws to be "jurisdictional" absent "sweeping and direct" language depriving the courts of jurisdiction. To that end, it is important to note that the statutory language in *Gallo* was *favorably* cited by that "more recent" Ninth Circuit precedent cited in *LULAC*, *see McBride Cotton & Cattle v. Veneman*, 290 F.3d 973 at 980 (9th Cir. 2002), as being a case involving the sort of sweeping jurisdictional language that precludes review. And a simple comparison of the language at issue in *Gallo* with the language in either § 346a(h) or § 348(g) makes clear that the FFDCA contains a far more sweeping, structured process for ensuring the completion of the administrative process prior to judicial review than the statutory language reviewed in *Gallo*.

---

[3] In addition, Congress added paragraph (h)(5) to clarify that (h)(1) provided the sole path for judicial review for issues subject to review under (h)(1). H. Rep. No. 104-669 (II) at 49 (1996). Because (d)(4) orders are subject to review under (g)(2) and (g)(2)(C) orders are subject to review under (h)(1), by the express terms of (h)(5), (d)(4) orders are not subject to review under any other provision of law.

FIFRA Standard and Process Issues

As noted above, the *LULAC* majority held that because FIFRA imports the FFDCA safety standard, the court could order both the revocation of all chlorpyrifos tolerances under FFDCA and the cancellation of all chlorpyrifos registrations under FIFRA in 60 days. That conclusion is legally flawed for two reasons. First, while FIFRA does indeed import the FFDCA food safety standard into the FIFRA "unreasonable adverse effects" standard, the food safety standard is but part of the FIFRA standard, and it is inapplicable to pesticides whose use will not result in residues on food. Specifically, 136(bb) provides:

> The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21 [i.e., the "reasonable certainty of no harm" standard]. . . .

The first part of the definition cited above is the so called "risk-benefit" standard that has been part of the FIFRA standard for registration and cancellation for over 40 years. That section effectively requires EPA to do cost-benefit balancing in deciding whether to regulate pesticides that are not governed by the FFDCA "risk only" food safety standard that is imported into the second part of the definition of "unreasonable adverse effects on the environment." Because chlorpyrifos products are registered for both food and non-food uses, the court should not have simply applied the FFDCA standard in determining that all chlorpyrifos registrations were also inconsistent with FIFRA. Rather, the appropriate standard for determining whether non-food use products should be cancelled is the "risk-benefit" standard. The FIFRA standard was not an issue put before the court and the court should not – and need not – have extended its ruling to compel specific any actions under FIFRA, much less by a date certain, as explained in more detail below.

Assuming for the sake of argument, however, that it was appropriate for the court to impose a FIFRA remedy, the court's direction for EPA to cancel all registrations within 60 days runs afoul of the process for FIFRA cancellation required under 7 U.S.C. § 136(d). As explained previously, at least 60 days prior to issuing any notice of intent to cancel a pesticide, EPA must first provide the United States Department of Agriculture and the FIFRA Scientific Advisory Panel with an opportunity to review the notice. *Id.* at § 136d(b). EPA must then provide the registrants of the pesticide with 30 days' notice of its intent to cancel the pesticide. *Id.* During that period, a person adversely affected by the notice may request a formal adjudicatory hearing, before an administrative law judge – and neither the statute nor the regulations place a temporal limit on the length of that proceeding. *See id.* § 136d(b), (d). Simply put, that process cannot practicably be completed within 60 days. Thus, any cancellation order (other than a voluntary cancellation) issued within 60 days will be procedurally flawed and will simply give rise to a pesticide registrant's challenge to any cancellation orders in federal court.

It should also be noted that if the purpose of the court's order respecting FIFRA registrations was to ensure an end to the use of chlorpyrifos on food, such a direction was likely unnecessary. Once a tolerance revocation becomes effective, any food treated with the pesticide after that date is "adulterated" under the FFDCA and may no longer move in commerce. 21 U.S.C. §§ 331(a), 342(a)(2)(B), 346a(a), (l)(5). Further, once a tolerance is revoked, § 346a(l)(1) directs EPA to coordinate the revocation of a tolerance with any necessary cancellation under FIFRA. It is also EPA's experience that a compelled cancellation action is generally not necessary once a tolerance revocation becomes effective since the registrant of the pesticide is unlikely to want to continue to market a product whose use will result in adulterated food and will therefore likely request voluntary cancellation.

If the court nonetheless believes that its order must address EPA's petition denial in full and must direct action with respect to FIFRA review of all chlorpyrifos products, irrespective of their approved uses, EPA believes the appropriate course of action would be for the court to order EPA to comply with FFDCA section 408(l)(1) with respect to "food use" products following any FFDCA tolerance revocation action, and to direct EPA on remand to determine whether the non-food use chlorpyrifos products are consistent with the FIFRA "risk-benefit" standard. Such an order would provide EPA with an opportunity to evaluate the remaining non-food uses under the FIFRA risk-benefit standard following tolerance revocation. To give the court some measure of comfort that EPA will complete these FIFRA activities in a timely fashion, the court could retain jurisdiction over the matter and require EPA to submit regular status reports.

Clarification of the Court's Remedy with Respect to the FFDCA

As noted, the court's direction that EPA revoke all tolerances does not address whether EPA is to issue a final order subject to subsequent administrative objections under § 346a(d)(4)(A)(iii) or a final reviewable order § 346a(g)(2)(C) that bypasses the administrative objections process entirely. EPA believes the latter approach would be inconsistent with the requirements of § 346a(g)(1) and (2), which provides to any person a right to submit objections following the issuance of tolerance revocation order and the right to request a stay of the effectiveness of the revocation if objections are filed. In addition, since the *LULAC* court vacated the Agency's final (d)(4)(A)(iii) order, EPA believes the current action pending before the Agency should be the resolution of the 2007 Administrative Petition, which would require EPA to issue a new final order. Because the issuance of a new (d)(4) final order would be subject to objections under the statutory process that could extend the final revocation date of the chlorpyrifos tolerances, EPA believes the Department should seek rehearing to request that the court clarify that it was directing EPA to issue a revocation order under § 346a(d)(4)(A)(iii) and that it did not intend to preclude the public and stakeholders from filing objections or requesting a stay of the effective date of the tolerance revocation under § 346a(g)(2).

ISSUES FOR REHEARING *EN BANC*

Federal Rule of Appellate Procedure 35 provides that rehearing *en banc* is disfavored and will not be granted unless such review is necessary to secure or maintain uniformity of the court's decisions or the proceeding involves a question of exceptional importance. The rule makes clear that this standard may be met when, among other things, a panel decision conflicts with a decision of the same circuit or an authoritative decision of another United States Court of Appeals that has addressed the issue. EPA believes rehearing *en banc* is appropriate in *LULAC* because the Panel's August 9 decision:

(1) conflicts with *Nader v. EPA*, 859 F.2d 747 (9th Cir. 1988), the decision discussed above addressing a nearly identical provision of the FFDCA;

(2) conflicts with the Second Circuit's decision in *NRDC v. Johnson*, 461 F.3d 164 (2d Cir. 2006), finding that 21 U.S.C. § 346a(h)(1) precludes direct judicial review of petition denial order;

(3) fails to identify a proper source of judicial review, unlike the cases it cites for support; and

(4) raises issues of exceptional importance by imposing a remedy that both exceeds the role of the federal judiciary in reviewing actions under the FFDCA and reviewing executive branch action generally.

Conflict within the Ninth Circuit

As discussed above in our request for panel rehearing, the majority's ruling in *LULAC* conflicts with *Nader*, a case not cited by the court. As noted, *Nader* addressed the judicial review provision of 21 U.S.C. § 348(g)(1), the section the § 346a(h)(1) provisions were modeled upon, and concluded that such language precludes a court of appeals from directly reviewing a petition for tolerance revocation. *Nader* has not been overruled and remains good law, notwithstanding the *LULAC* majority's suggestion that parties should cite with caution cases finding jurisdictional limitations in light of recent Supreme Court and Ninth Circuit case law admonishing "'against profligate use of the term jurisdictional.'" *LULAC*, slip op. at 24 (quoting *Merritt v. Countrywide Fin. Corp.*, 759 F.3d 1023 at 1039 (9th Cir. 2012)). However, as noted above, the statutory scheme created by §§ 346a(g) and 346a(h)(1) that only provides for judicial review of EPA's order on objections is precisely the sort of sweeping and direct provision that the more recent Ninth Circuit decisions have agreed is jurisdictional.

Further it should also be noted that *LULAC* conflicts with the recent observation of the mandamus panel in *In re PANNA*, 863 F.3d 1131 1133 (9th Cir. 2017) that rejected petitioners' motion for additional mandamus relief. In so doing, the court also stated that, "Now that EPA has issued its denial, substantive objections must first be made through the administrative process mandated by statute. PANNA implicitly recognizes as much by acknowledging that '[f]iling objections and awaiting their resolution by the EPA Administrator is a prerequisite to obtaining judicial review' of EPA's final response to the petition. Only at that point may we

consider the merits of EPA's 'final agency action.'" *Id.* While this language may be dicta, the *LULAC* majority's dismissal of this statement as going only to exhaustion and not jurisdiction is hard to fathom.

Conflict with the Second Circuit

The *LULAC* dissent correctly notes that the majority's decision conflicts with the Second Circuit's decision in *Natural Resources Defense Council v. Johnson*, 461 F.3d 164 (2d Cir. 2006). In *Johnson*, the Second Circuit upheld district court's holding that it could not review claims under § 346a(h), as jurisdiction under that provision is limited to the courts of appeals. In a sweeping ruling, the Second Circuit made clear not only that judicial review under 346a(h)(1) is limited to the courts of appeals, but that the provision "forecloses such review prior to the exhaustion of administrative remedies." *Id.* at 173. Interestingly, the *Johnson* court favorably cited the Ninth Circuit's decision in *Nader* in support of its holding, specifically referencing the portion of the decision addressing the jurisdictional nature of the parallel provision of § 348(g). *Id.* The Johnson court's favorable citation of *Nader* in support of its holding casts doubt on the *LULAC* majority's suggestion that because *Johnson* simply held that the district court lacked jurisdiction, the matter of the court of appeals' jurisdiction was perhaps not squarely addressed in *Johnson*. *LULAC*, slip op. at 21.

Failure to Identify a Proper Source of Judicial Review

The *LULAC* majority's jurisdictional finding is exceptional not simply because it conflicts with the position of every other court that has evaluated the language of section § 346a(h)(1), but because its reliance on that section itself as the supposed source of jurisdiction takes the court out of step with all the cases it cites in support of its jurisdictional finding. As noted above, section § 346a(h)(1), by its terms, only provides for review of section § 346a(g)(2)(C) orders on objections; it does not provide a basis for review of any action taken under § 346a(d)(4) (i.e., a final rule establishing or revoking a tolerance or a petition denial order); and § 346a(h)(5) precludes petitioners from seeking review under any other provision of law. Therefore, there is no provision in the FFDCA or any other law that allows for direct judicial review of the March 29, 2017 denial order. Thus, to find jurisdiction, the court had to essentially read the actions listed in § 346a(d)(4) (final tolerances, revocations and petition denial orders) into the text of § 346a(h)(1), notwithstanding the very clear statutory scheme that provides a path for judicial review only though the submission and review of administrative objections under § 346a(g)(2)(C) following those actions—and provides no path for direct review of those actions themselves. In the cases cited by the *LULAC* majority for support, however, the courts found jurisdiction not in the very provisions that addressed the need to exhaust administrative remedies, but in other provisions of federal law purporting to provide the courts with jurisdiction. Thus, the other courts were attempting to reconcile provisions requiring the exhaustion of remedies with other provisions of federal law clearly granting the courts subject matter jurisdiction. In contrast, under the FFDCA, there is no other provision of federal law providing jurisdiction except § 346a(h)(1), which limits review of § 346a(d)(4) petition denial orders to those that have proceeded through the §346a(g)(2) objections process.

The case perhaps most heavily relied upon by the majority, *Verizon Maryland Inc. v. PSC*, 535 U.S. 635 (2002), is also the clearest example of the *LULAC* majority's misuse of precedent. *LULAC* relied on the Court's statement in *Verizon* that the mere fact that a statute makes some acts reviewable does not preclude review of other acts not expressly mentioned as

reviewable. Slip op. at 20. But the *LULAC* majority ignores that in the absence of the putative exhaustion requirement, the *Verizon* court clearly had jurisdiction from another source of law:

> Verizon's claim thus falls within 28 U.S.C. § 1331's general grant of jurisdiction, and contrary to the Fourth Circuit's conclusion, nothing in 47 U.S.C. § 252 (e)(6) purports to strip this jurisdiction. Section 252(e)(6) provides for federal review of an agreement when a state commission "makes a determination under [§ 252]." If this does not include (as WorldCom, Verizon, and the United States claim it does) the interpretation or enforcement of an interconnection agreement, then § 252(e)(6) merely makes some other actions by state commissions reviewable in federal court. This is not enough to eliminate jurisdiction under § 1331.

Verizon at 643. Notably, the *Verizon* court continued:

> And finally, none of the other provisions of the Act evince any intent to preclude federal review of a commission determination. If anything, they reinforce the conclusion that § 252(e)(6)'s silence on the subject leaves the jurisdictional grant of § 1331 untouched. For where otherwise applicable jurisdiction was meant to be excluded, it was excluded expressly. Section 252(e)(4) provides: "No State court shall have jurisdiction to review the action of a State commission in approving or rejecting an agreement under this section." In sum, nothing in the Act displays any intent to withdraw federal jurisdiction under § 1331; we will not presume that the statute means what it neither says nor fairly implies.

Id. at 644. It would be hard to make such a statement about the FFDCA given the language in § 346a(h)(5) that precludes review under any other provision of law. There is plainly, therefore, no source of jurisdiction the *LULAC* panel can properly cite to that allows it to review petition denial orders under § 346a(d)(4).

The Court's Remedy Exceeds the Role of the Courts Under the FFDCA in Reviewing Agency Action Generally

While, for reasons explained above, EPA believes the court did not have jurisdiction, even assuming the court had jurisdiction and properly ruled on the merits of the case, the remedy imposed by the court is inconsistent with the judicial review provisions of the FFDCA and vastly exceeds the limited review the Supreme Court and the Ninth Circuit have directed lower courts to exercise over executive branch agencies. Under § 346a(h)(2), the courts of appeals are given exclusive jurisdiction "to affirm or set aside the order or regulation complained of in whole or in part." Nothing in that provision authorizes the court, upon such a finding, to then substitute its judgment and direct EPA to take a specific form of action.

In that respect, review under the FFDCA mirrors the limited review that courts are to exercise over executive branch agencies generally under the Administrative Procedure Act. As the Supreme Court has made clear, courts should not substitute their judgment for the agency's, but should remand matters that are inconsistent with law or the standard of review. *See Camp v. Pitts*, 411 U.S. 138, 143 (1973) (if finding is not sustainable on the record, decision must be

vacated and the matter remanded or further consideration). *National Wildlife Fed. v. US Army Corps*, 384 F. 3d 1163 at 1170 (9th Cir. 2004) ("Our review of agency action is governed by the APA. . . . The standard is a narrow one, and we may not substitute our judgment for that of the agency."). In *LULAC*, the majority ignored this edict and decided for itself that all chlorpyrifos tolerances must be revoked and all chlorpyrifos registrations cancelled within 60 days. The court did so even though EPA had not completed the rulemaking process on its prior proposal to revoke tolerances nor had it completed the objections process on the Agency's subsequent decision to deny the Administrative Petition. While EPA does not dispute that the 2016 risk assessment suggests that tolerance revocation is appropriate, that assessment was conducted for a *proposed* rule and did not benefit from EPA's review of the rulemaking comments or the subsequent objections to the March 2017 denial order that would be considered were the court to have properly remanded the matter to EPA to complete the statutory review process. Further, as noted above, the court's rush to impose its own judgment resulted in the court overlooking the need for EPA to follow FIFRA and FFDCA procedures in cancelling product registrations and revoking tolerances and it misapplied the FIFRA registration standard in determining that all products must be cancelled. These findings were plainly in error and the Department should ask the Ninth Circuit to reject the *LULAC* court's remedy and follow established Supreme Court and Ninth Circuit precedent in its review of EPA's action.

ADVERSE IMPACTS ON EPA PROGRAMS AND BEYOND

The tolerance setting and revocation process in the FFDCA is unique among the laws EPA administers in that much of the important administrative process occurs after the issuance of a rule or a petition denial. The majority of petitions EPA receives are requests for establishment of tolerances. In those instances, EPA generally does not issue a proposed tolerance, but issues a final tolerance based on data provided in the tolerance petition after publishing notice that the petition requesting tolerances was submitted. 21 U.S.C. § 346a(d)(4)(A)(i). Similarly, when EPA determines that a petition should be denied, it typically publishes an order without a proposal of that decision. *Id.* at § 346a(d)(4)(A)(ii).[4] As a result, stakeholders and the public generally do not have an opportunity to comment on EPA's risk assessment of the pesticide or safety determination in advance of the final tolerance action, and EPA therefore does not have the benefit of that input in issuing its final regulation or order. The objections process therefore plays a critical role in both giving persons who oppose EPA's action a chance to provide input into the process and, importantly, it gives EPA a chance to either "correct its own errors" or "produce a useful record for subsequent judicial consideration, especially [as is the case for chlorpyrifos] in a complex or technical factual context." *LULAC* at 27-28. The majority's decision in *LULAC* rested its disregard of the strong institutional interests in maintaining the statutory process specifically on the facts presented in this case. The result is a

[4] While § 346a(d)(4)(A)(ii) authorizes EPA to issue a proposal in response to a petition requesting establishment, modification, or revocation of a tolerance, use of that mechanism is limited due to tight review deadlines EPA faces for completing registration and tolerance actions under the Pesticide Registration Improvement Act, as codified at 7 U.S.C. § 136w-8.

decision that threatens to upset in other cases an extremely important process by allowing challenges to final tolerance rules and petition denials in advance of the objections process, depriving EPA of an opportunity to correct itself if it is in legal or factual error or develop a defensible response to the objections and a meaningful record for judicial review. While the decision does not foreclose exhaustion arguments EPA might make regarding the need to complete the objections process prior to judicial review, because of this decision, EPA has no doubt that it will be facing litigation much earlier in the process on records that are less defensible—and that would impose greater burdens on judicial resources to address unresolved complex or factual technical issues—than were it allowed to complete the administrative objections process without facing litigation.

Further, EPA is concerned that the *LULAC* majority's sweeping jurisdictional and exhaustion holdings and expansive remedy determination could have adverse consequences across the Agency (and even for other agencies) by spawning numerous new cases in the Ninth Circuit from litigants seeking to have the courts allow them to forego statutory and regulatory procedures and direct, rather than simply review, final agency action. While EPA understands that its considerable delay in acting on the petition may have been the source of the court's decisions to find jurisdiction and exhaustion and to direct the final action EPA must take, there is no guarantee that courts in the Ninth Circuit will confine their reliance on *LULAC* to similar circumstances. It also bears mentioning that EPA's compliance with the court's direction will undoubtedly result in litigation against EPA by registrants and growers who will be deprived of procedural rights under the FFDCA and FIFRA if EPA is compelled to issue final revocations and cancellations in 60 days, and that the defensibility of any future action EPA may take in this regard will be significantly impaired if this opinion (and especially its remedy) stands.

CONCLUSION

For the reasons articulated above, EPA requests that the Department seek both panel rehearing and rehearing *en banc* on the issues identified in this letter. For further information, please contact me or Mark Dyner at 202-564-1754.

Sincerely,

Matthew Z. Leopold
General Counsel